REMARKS

Reconsideration is requested.

Claims 1-9 and 17-23 have been canceled, without prejudice.

Claims 10-16 will be pending upon entry of the present Amendment.

The Section 112, second paragraph, rejection of claims 1-23 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments as well as the above amendments.

With regard to the Examiner's comments in paragraph A on page 5 of the Office Action dated January 14, 2004 (Paper No. 14), claim 10 has been amended according to the Examiner's suggestion, to advance prosecution. Claim 17 mentioned in paragraph A on page 5 of Paper No. 14 has been canceled, without prejudice, to advance prosecution.

With regard to the Examiner's comments relating to the alleged indefiniteness of the phrase "immobilizing phase" in claim 10, the Applicants respectfully submit that the Examiner's own comments evidence an appreciation of the meaning of the objected to phrase. Specifically, the Examiner comments that the claim is directed to "the immobilization of a formed binding complex." Accordingly, one of ordinary skill in the art will appreciate that the immobilization of the formed binding complex is facilitated by the recited immobilizing phase. No further amendments to the claim are believed to be required.

As for the Examiner's comments relating to claim 20 in paragraph C on page 5 of Paper No. 14, claim 20 has been canceled, without prejudice, making the rejection of the same moot.

Reconsideration and withdrawal of the Section 112, second paragraph, rejection of claims 10-23 are requested.

The Section 112, first paragraph, rejection of claims 17-23 will be moot upon entry of the present Amendment.

To the extent not obviated by the above amendments, the Section 102 rejection of claims 10-13 and 17-20 over Heggli (GB 2217335A), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

Initially, the Applicants urged the Examiner to appreciate that an important technical feature of the presently claimed method is to determine the CRP by sandwich assay having the following construction:

Immobilized anti-CRP antibody-CRP-labeled PC, as shown in Figure 1B.

The presently claimed invention has provided, for the first time, an accurate assay of not only serum CRP concentration during an acute phase reaction, such as in the occurrence of infection, inflammation and tissue damage, but also serum CRP concentration within a normal range. See, page 16 of the present application.

The Examiner's reliance on Heggli is submitted to be misplaced as the references are not believed to teach each and every aspect of the presently claimed invention. Specifically, the system described in Heggli provides a PC residue which is first immobilized and then bound by CRP. As a final step in the method of the cited art, a second CRP-binding signal substance is bound for detection. That is, the construction of the detection system of Heggli is as follows:

Immobilize PC-CRP-a second CRP-binding signal substance.

This configuration is similar to the schematic of Figure 1C of the present application.

The Applicants respectfully submit that the above clearly demonstrates the distinction between the presently claimed invention and the method of Heggli such that the method of recited art failed to teach each and every aspect of the presently claimed invention. Withdrawal of the Section 102 rejection therefore of claims 10-13 and 17-20 over Heggli is requested.

The Section 103 rejection of claims 10-13 and 17-20 over Siboo (Journal Immunological Methods, 23, 1978, pp 59-67) in view of Robey (The Journal of Biological Chemistry, Vol. 258, No. 63/25/83, pp 3895-3900), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments. Moreover, the Section 103 rejection of claims 14-16 and 21-23 over Heggli in view of Hemmila (Analytical Biochemistry, 137, 335-343, 1984), is traversed. The Section 103 rejection of claims 14-16 and 21-23 over Siboo in view of Robey and Hemmila is similarly traversed. Reconsideration and withdrawal of the Section 103 rejections are requested in view of the following distinguishing comments.

The Applicants understand the Examiner to believe that Siboo et al describes a method for detecting CRP on the basis of the principal of utilizing immobilized anti-CRP antibody-CRP-a second anti-CRP labeled complex and that the Examiner believes Robey describes that PC binds to CRP and that labeled PC can be used in an assay for CRP. The Examiner is understood to conclude that it allegedly would have been obvious for one of ordinary skill in the art to apply the labeled PC of Robey in place of the second anti-CRP labeled complex of Siboo.

The Applicants respectfully submit that the presently claimed invention would not have been obvious from the combination of the cited art.

Specifically, the presently claimed invention provides a method for detecting CRP with high sensitivity which was not available by the prior art method. The Examiner is again requested to see Figure 1 of the present application which illustrates the mechanism of the method of the presently claimed invention as well as those of the prior art.

That is, Figure 1 of the present application provides the following:

(A) antibody-antibody method control (method of Siboo)

(B) antibody-PC method (present invention)

(C) PC-antibody method control (method of Heggli).

Upon review of Figure 1 of the present specification, the Examiner will appreciate that the present application describes the method of the present invention (Figure 1(B), for example) which provides for the detection of CRP with a greater degree of sensitivity compared to the methods of Figures 1(A) and (C). Further, the presently claimed method has provided a relatively easy and rapid detection method for CRP as compared to using, for example, a second antibody. The Examiner is further referred to the present application at page 15, line 17 to page 16, line 24 for further descriptions of the advantages of the presently claimed method.

More specifically, as can be understood from Figure 2 of the present application, the results of the CRP assay by the presently claimed method provided a broad range of 5 to 500 ng CRP/ml (Figure 2A). The range was far greater than ranges detected by the methods of the above-indicated methods (A) and (C). See, Figure 2b.

The presently claimed method has provided therefore for the first time, accurate assay of serum concentration within a normal range, which is less than 350 ng/ml, as well as serum CRP concentrations during an acute phase reaction. None of the cited references, alone or combined, describes or suggests the presently claimed invention or its advantages.

In view of the above, the Applicants respectfully submit that the claims are patentable over the cited art and withdrawal of the Section 103 rejections are requested.

For completeness, attached is an English translation of the Applicant's priority document JP 55352/1999. Acknowledgment of receipt of the same is requested in the Examiner's next communication.

The Examiner is requested to contact the undersigned if anything further is required to advance the present application to allowance.

Respectfully submitted,

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